



December 15, 1999



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Promotes cell integrity and function.
- (2) Sesame oil contains several important antioxidants, sesamolin and sesamol, that are believed to promote the integrity of body tissues in the presence of oxidizing compounds. The antioxidants sesaminol and sesamolinol maintain fats, including low-density lipoproteins (LDL), in an unoxidized state.
- (3) Vitamin E, a fat-soluble antioxidant, protects the body from harmful oxidizing compounds. The sesaminol and sesamin found in sesame oil, increases vitamin E activity dramatically, acting synergistically with vitamin E to provide antioxidant capacity to the body.
- (4) Maintains a healthy liver.
- (5) Keeps your heart healthy.

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- (6) Animal research suggests that supplementation with sesamin may help maintain normal blood fat levels by regulating the secretion of fats from the liver.
- (7) Sesamin, through its effect on regulating compounds known as eicosanoids, helps promote a balanced immune and auto-immune response.

These statements are made for a dietary supplement containing ingredients of gelatin, glycerine, water, and carob. The name of the product is Sesame Seed Oil.





The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.



